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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,723	02/27/2004	Chul-Wook Kim	P/4535-3	9540

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,723	KIM ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending

Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-3 and 10 are examined on the merits.

Election/Restrictions

1. Applicant's election with traverse of Claim 3 in the reply filed on 01/25/2006 is acknowledged. The traversal is on the ground(s) that the different inventions are similar and should be prosecuted together. This is not found persuasive because the Examiner maintains that each of claims 3-9 recites a distinct collection of genes that is not required for any of the other claims, thus a search for one collection is not coextensive with a search for any other collection.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear because of the term 'a probe' in claim 1. It is unclear how a single probe would be capable of analyzing the multiple genes specifically expressed in the muscle and fat tissues of swine.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-1111 (also available at www.uspto.gov).

The invention is drawn to a cDNA chip capable of detecting: genes specifically expressed in the muscle and fat tissues of swine (claims 1-3 and 10); 4434 ESTs derived from muscle and fat tissues of swine (claim 2); and 29 marker genes that are identified by gene names (e.g.: actin) (claim 3).

When the claims are analyzed in light of the specification, the instant invention encompasses a wide variety of genes and transcripts. The cDNA chip of claim 1 encompasses probes capable of detecting any gene that is expressed in the muscle

and fat tissue of swine under any conditions, such as different physiological or pathological conditions. Such probes would encompass nucleic acids corresponding to any gene that is expressed at any level in swine tissue. Similarly, the probes of claim 2, encompass probes directed to any EST sequence from swine tissue. Regarding the specifically named genes of claim 3, considering the example of 'Actin', the claimed gene name includes different members of a multigene family (Engel et al (1982)) and polymorphic size variants (Schmitz et al (1994)). Within the specification, Table 1 (p.21-22) lists six entries for 'Actin', with corresponding EST Nos. as well as Accession Nos. None of the six 'Actin' Accession Nos. are swine genes (BAB19361, lamprey; AAA51586, human; P53506, frog; AAF20165, *Arabidopsis*; B25819, *Danio*; X52815 rat). Additionally, four of the Accession Nos. correspond to polypeptide sequences (BAB19361, lamprey; AAA51586, human; P53506, frog; AAF20165, *Danio*); and thus may encompass an enormous number of nucleic acid sequences that may encode the polypeptides of the disclosed GenBank Accesion No.

However, the specification does not disclose any SEQ ID NOs corresponding to the ESTs Nos. from swine listed in Table 1, and discloses only SEQ ID NO: 1-5 as genes specifically expressed in the muscle and fat tissues of swine. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, there is no disclosure of nucleotide sequences by SEQ ID NO of any probe structures or EST sequences for the genes listed in Tables 1 and 2; claim 2 is drawn to a cDNA chip comprising 4,434 EST derived probes, however the

instant application contains no written description of any such ESTs. For example, the specification does not provide any disclosure as to what is detected with an 'Actin' probe, or to what sequence a probe directed to, for example EST No SM635, would be expected to hybridize. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, there is no disclosure of the identifying characteristics of any tissue specific genes, ESTs, any of the named marker genes of claim 3, or the probes that may be used to detect the expression of the genes.

In conclusion, the limited information supplied by the instant specification (i.e. SEQ ID NOs: 1-5, gene name and the disclosure of GenBank Accession numbers) is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a cDNA chip for the functional analysis of tissue specific genes, tissue specific ESTs, or the 29 differently named marker genes of claim 3 at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (1995) (US Patent 5,474,796).

The claims of the instant application are broadly drawn to a chip for the analysis of swine genes. Brennan teaches a microarray that contains 10-mer polynucleotides spotted at a discrete location such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, lns. 48-55). Such an array would inherently comprise probes capable of detecting genes expressed in swine.

Regarding claims 1 and 2, the array of Brennan would inherently be capable of detecting marker genes specifically expressed in the muscle and fat tissues of swine (relevant to claim 1), and would also include probes capable of detecting ESTs derived from the muscle and fat tissues of swine (relevant to claim 2).

Regarding claim 3, the comprehensive nature of the 10-mer array of Brennan would make the array thus capable of detecting any of the named cellular structure and motility related genes asserted by the instant application to be specifically expressed in muscle and fat tissues.

Regarding claim 10, reading the claims as broadly as they are written, the array of Brennan is a kit (i.e. a collection of compositions) for analysis of swine genes.

8. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al (2001).

Regarding claims 1-3, Yamamoto teaches a membrane (which is a substrate) containing immobilized swine genomic DNA, wherein the DNA is digested with restriction enzymes and separated on a 1% agarose gel prior to transfer to the solid support (Fig 1; p.3309, left col., lns.11-22). The immobilized pig genomic DNA necessarily includes probes capable of detecting genes specifically expressed in the muscle and fat tissues of swine (relevant to claim 1), as well as probes that include any EST derived from swine (relevant to claim 2) and probes capable of detecting any of the 29 named genes recited in claim 3.

Regarding claim 10, reading the claims as broadly as they are written, the Southern blot of Yamamoto et al is a kit (i.e. a collection of compositions) for analysis of swine genes.

9. Claims 1, 2 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yao et al (2002).

Yao et al teaches the construction of a cDNA library from porcine skeletal muscle (p.213, ln.5).

Regarding claims 1, 2, and 10, Yao et al teaches that RNA was isolated from the skeletal muscle of pigs, amplified by RT-PCR, and then the collection of fragments was cloned into a plasmid vector (p.213, lns.12-23). The reference also teaches the analysis of the cDNAs by Southern blot analysis. Yao et al teaches that aliquots of plasmid DNA from the library are digested to liberate the insert, separated on a 1% agarose gel, then blotted onto a Zeta-probe membrane (p.214 – Southern blot analysis;

p.215, last paragraph). The membrane containing the separated library (Fig 1) is thus a cDNA chip (i.e. a substrate upon which cDNA probes are immobilized) comprising probes capable of detecting genes specifically expressed in tissues of swine (relevant to claim 1). Relevant to claim 2, Yao et al teaches that the library is estimated to contain $2x10^6$ independent clones (p.215, ln.14), and would thus membrane for Southern analysis of the library would include 4434 ESTs. Relevant to claim 10, reading the claims as broadly as they are written, the Southern blot of Yao is a kit (i.e. a collection of compositions) for analysis of swine genes.

10. Claims 1, 2, and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bai et al (2003).

Bai et al teaches a porcine skeletal muscle cDNA microarray. The reference teaches that inserts from two porcine skeletal muscle λZAP-Express cDNA libraries (p.11, left col., lns.8-11) were amplified to create probe DNA that was immobilized on a glass slide (p.11, left col., lns.37-50).

Regarding claim 1, the array taught by Bai et al is a cDNA chip (a collection of cDNA-specific probes immobilized on a substrate of CMT-GAPS coated slides), and it is capable of detecting genes specifically expressed in swine tissues (p.11 – Red-white muscle microarray hybridization).

Regarding claim 2, Bai et al teaches that a total of 5,500 clones from a cDNA library were selected for microarray assembly (p.2, right col., lns.8-11). Because the

clones originate from a cDNA library (p.11, left col., lns.8-16), the amplified DNA used for the array are ESTs.

Regarding claim 10, reading the claims as broadly as they are written, the array of Bai et al (p.11 – Construction of porcine skeletal muscle cDNA microarray) is a kit (i.e. a collection of compositions) for analysis of swine genes.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-3 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to cDNA chips, and kits containing said chips, capable of the detecting markers genes specifically expressed in the muscle and fat tissues of swine. The specification asserts that the claimed inventions relate to a technique for screening swine genes and analyzing there functions, and is useful for swine improvement (p.1; p.7); and further asserts that the object of the present invention is to provide a means for the comparison of gene expression according to breeds and tissues, mutation screening and polymorphism interpretation, drug development and disease treatment (p.7). The specification states that the objectives are accomplished by examining profiles of genes specifically expressed in swine tissues (p.8). However, there is no teaching in the specification, nor any indication in the prior art, as to how an

analysis of genes expressed in muscle and fat tissues (claims 1 and 10), or an analysis of 4,434 unnamed and ESTs for which there is no description (claim 2), or an analysis of the expression of the 29 named genes of claim 3, would in be specifically informative with regard to swine improvement, or be indicative of the other asserted objectives of the invention, for example the development of a new drug for treatment of diseases, or any other useful phenotype. Furthermore, the listing of named genes (claimed 3) includes such titles as '19 kDa-interacting protein 3-like', for which there is no teaching in either the specification or the prior art as to what sort of analysis of expression would be required to draw any conclusion concerning any of the asserted objectives of the claimed invention.

Therefore, the asserted utilities of swine gene analysis to the claimed products (i.e. a cDNA chip containing probes for detecting genes expressed in the muscle and fat tissue of swine (claim 1), 4,434 unnamed ESTs (claim 2), or the 29 named genes of claim 3) are not considered specific or substantial, as the claimed cDNA chips would not provide information that is biologically relevant with regard to the asserted utilities. Thus, there would be a burden on the artisan using the claimed product for the analysis swine gene expression to determine a specific and substantial utility for data generated by the analysis of swine gene expression using the claimed invention. The asserted utilities, therefore, do not constitute a substantial utility for the claimed invention, since further experimentation would be required to establish a real world use for the claimed invention.

Claim 1-3 and 10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/785,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chips (claims 1-4) and a kit comprising the same chip (claim 5) comprising probes directed to genes expressed in the muscle and fat tissues of swine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/788,562. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chips (claims 1 and 2) and a kit comprising the same chip (claim 3) comprising probes directed to genes expressed in the muscle and fat tissues of swine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/785,981. Although the conflicting claims are not identical, they are

not patentably distinct from each other because they are overlapping in scope and subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chips (claims 1 and 2) and a kit comprising the same chip (claim 5) comprising probes directed to genes expressed in the muscle and fat tissues of swine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowable. No claim is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER